IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 59

(Order on Plaintiffs' Motion to Compel Deposition Testimony)

Currently pending before the court is Plaintiffs' Motion to Compel Deposition Testimony, filed February 19, 2010. (Docket # 301.) The parties have responded (# 318) and replied (# 323), and the court conducted a hearing on April 13, 2010.

Arguments of the Parties

In their Motion, Plaintiffs seek an order compelling the Actavis Defendants to answer deposition questions pertaining to the production, manufacturing processes, current good manufacturing practices ("cGMP"), quality control and quality assurance of *all* pharmaceuticals produced at the Actavis Totowa facilities during the relevant time period, pursuant to Rule 37(a)(3)(B)(i) of the Federal Rules of Civil Procedure. (# 301, p. 1.) Plaintiffs assert that the Actavis Defendants engaged in uniform practices and procedures in their manufacturing and quality departments for all drugs, including Digitek®. (# 301, p. 3.) Regarding the quality department in particular, Plaintiffs point out that it functioned for Actavis Totowa out of the Little Falls Facility and the

Riverview Facility. Like the manufacturing department, many of the processes, procedures and personnel in the quality department were interchangeable and uniform for all drugs. In other words, personnel trained to conduct quality testing on Digitek® also were qualified to conduct such testing on the many other products made by Actavis. (# 301, p. 5.) Notably, the FDA found significant issues with the quality unit at Actavis Totowa's Riverview facility. (# 301, p. 5.) Plaintiffs complain that when they have attempted to question the Actavis Defendants about violations of the cGMP and the findings of the FDA inspections, the Actavis Defendants have instructed their witnesses not to answer or to answer only as to Digitek®. (# 301, p. 6.) Plaintiffs assert that the FDA inspections and observations concerning cGMP violations were general and broad in nature, and that such deficiencies clearly affected Digitek®. (# 301, pp. 7-8.) In short, according to Plaintiffs, the vast majority of violations cited by FDA inspectors were system-wide and not limited to a specific product. (# 301, pp. 7-8.)

Plaintiffs point out that the Actavis Defendants improperly rely on PTO # 12, the protective order, as justification for keeping witnesses from answering questions. Plaintiffs contend that PTO # 12 and the provision allowing for redaction of some information applies only to produced documents, material and other things, not witness testimony. (# 301, p. 9.) Plaintiffs further

assert that the testimony they seek is relevant and related to the claims set out in the master complaint. They note that the master complaint alleges violations of regulations concerning good manufacturing practices and gives examples of regulations defendants may have violated. (# 301, p. 10; # 73 ¶¶ 43, 94.)

Finally, Plaintiffs assert that the Affidavit of Richard Dowling calls into question the rationale behind the court's denial of an earlier motion to expand discovery filed by Plaintiffs (# 150), PTO # 27. (# 301, p. 11.) Mr. Dowling stated in an Affidavit that "[e]ach time Digitek® is manufactured, the Stokes BB2 45 station press is customized using very unique 'tooling' - punches and dies - designed solely and used exclusively for the purpose of manufacturing Digitek® on that tablet press." (# 146, p. 32.) During Mr. Dowling's deposition, he was questioned about an e-mail dated December 18, 2007, in which he stated that

> [a]s part of the corrective action for investigation number 07-093 for Digoxin double tablets, I am going to state that we buy a complete set of lowers and dies for both strengths of Digoxin that will be dedicated and not used for any other products. It is possible the tablet stuck to the punch and was double compressed. In addition, we should immediately do the same for the three strengths of - blank or redacted - right away.
>
> In the long run, the lower punches and dies will last longer if they are dedicated and not used by multiple products and we won't have to delay set-ups because the lower dies needed are in use and not available[.]

(# 301, p. 11.) Plaintiffs contend that the undersigned "placed significant weight on Mr. Dowling's affidavit in rendering her

ruling in PTO # 27, even stating that '[M]r. Dowling's affidavit states that the tools and dies used for tablet compression of Digitek® are utterly unique.'" (# 301, p. 12 (quoting PTO # 27, p. 13).) Plaintiffs assert that based on Mr. Dowling's subsequent contradictory testimony, the information relied upon in PTO # 27 is fundamentally flawed. (# 301, p. 12.)

In response, the Actavis Defendants point out that Plaintiffs' motion is "untethered to any specific question or enumerated questions as contemplated by Rule 37[a](3)(B)." (# 318, p. 1.) Defendants assert that Plaintiffs' Motion is nothing more than a motion for reconsideration of PTO ##s 27 and 37 and should be denied. (# 318, p. 1.) The Actavis Defendants assert that they have complied with these PTOs by allowing deposition testimony as to Digitek® and general practices and procedures at Actavis Totowa, but have objected to testimony into facts and circumstances specific to the manufacture and production of non-Digitek® products. (# 318, p. 1.)

The Actavis Defendants argue that Plaintiffs' motion to expand discovery was "in no way limited to document production. It sought an expansion of the scope of *all* discovery ...." (# 318, p. 2.) In PTO # 27, ruling on Plaintiffs' motion to expand discovery, the Actavis Defendants assert that the undersigned rejected Plaintiffs' contention that an incident involving one product would be similar or even identical to an incident involving Digitek®. Although the

court allowed records of Little Falls production and the use of equipment for products other than Digitek® which immediately preceded the use of that equipment for production of Digitek®, the Actavis Defendants assert that "[n]othing in the court's order limits its finding only to document production. PTO No. 37 affirmed PTO No. 27."[1] (# 318, p. 3.) The Actavis Defendants assert that PTO ##s 27 and 37 require denial of Plaintiffs' Motion. (# 318, pp. 5-7.)

The Actavis Defendants further assert that Plaintiffs can obtain the type of non-Digitek®-specific testimony they seek within the confines of PTO ##s 27 and 37, arguing that they have "always allowed general questioning about manufacturing processes, GMPs, quality control and quality assurance at the Actavis Totowa facility, and with respect to Digitek®." (# 318, p. 7.)

Finally, the Actavis Defendants argue that PTO ##s 27 and 37 are not undermined by the deposition of Mr. Dowling. Mr. Dowling's Affidavit speaks to the unique manufacturing system used to produce Digitek®. The Actavis Defendants assert that Plaintiffs attempted to isolate portions of Mr. Dowling's Affidavit and that when reviewed in its entirety, there is no discrepancy or false statement within the Affidavit. The Actavis Defendants explain that when read in its entirety, Mr. Dowling's Affidavit makes clear

[1] The Actavis Defendants note that in November 2009, Plaintiffs attempted unsuccessfully to expand the scope of discovery in Pennsylvania. The Honorable Sandra Mazer Moss denied such request, cited PTO # 27 and provided the very same narrow exception. (# 318, p. 4.)

that in referencing the "very unique 'tooling' - punches and dies - designed solely and exclusively for the purpose of manufacturing Digitek® on that tablet press," Mr. Dowling also stated that the tooling consists of a complete set of three pieces, the upper punch, a lower punch and a die. The upper punch contains a marking on the tip which results in each individual Digitek® tablet being embossed with an appropriate label corresponding to its product identification number. According to the Actavis Defendants, Plaintiffs ignore the fact that Mr. Dowling's reference to "tooling" was expressly defined to include the upper punch, the lower punch and the die, while Mr. Dowling's e-mail referred only to the lower punch and the die and makes no reference to the upper punch or the system into which these components are integrated to produce Digitek®. (# 318, pp. 10-12.)

In reply, Plaintiffs assert that they do not seek reconsideration of PTO ##s 27 and 37. Instead, they seek an order pursuant to Rule 37(a)(3)(B)(i) to compel the Actavis Defendants to answer basic factual questions material to manufacturing and quality department practices and procedures at the Actavis Totowa facilities. Plaintiffs point out that many of the depositions were not scheduled until long after the time for reconsideration of PTOs ## 27 and 37 had passed. (# 323, p. 2.) Plaintiffs dispute the Actavis Defendants' assertion that they have permitted unrestrained questioning regarding manufacturing, production, current good

manufacturing practices, quality control and quality assurance procedures and systems. (# 323, p. 5.) Finally, Plaintiffs assert that Mr. Dowling's Affidavit casts doubt on the rationale behind PTO # 27. (# 323, pp. 5-9.) Plaintiffs assert that

> the "unique tooling" proffered by defendants includes dies and lower presses interchangeably used to produce other products with the same die characteristics, sizes, punches, and tablet configurations and an upper punch "unique" to Digitek® because it embosses the Digitek® emblem on the tablet.
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> Even accepting Defendants unique upper punch position as true, Mr. Dowling's deposition testimony is directly at odds with the affidavit relied upon by Magistrate Judge Stanley in issuing PTO No. 27 .... Indeed, even if only the upper punch is unique, then Mr. Dowling should have set forth that information in his affidavit instead of misleading information about two separate component parts that are not unique.

(# 323, p. 8.)

Previous Relevant Orders

A brief review of the orders relevant to the instant Motion is necessary for a full understanding of the issues at hand. On February 5, 2009, PTO # 12, the stipulated protective order, permitted redaction from produced documents, materials or other things, "[a]ny information relating to products other than Digitek, unless manufacturing information about a product other than Digitek is reasonably related to Digitek manufacturing ...." (# 71, p. 5.)

In PTO # 27, entered July 1, 2009, and affirmed by the presiding District Judge in PTO # 37 on August 10, 2009, Plaintiffs sought an order expanding discovery from Digitek® only to all

manufacturing processes of the Actavis Totowa Little Falls, New Jersey facility for all product lines. Based in part, upon the Affidavit referenced above from Mr. Dowling, the undersigned declined to permit the expansive discovery sought by Plaintiffs. However, the court did find that Plaintiffs have

> shown good cause for a modest expansion of the scope of discovery to include records of Little Falls production and the use of equipment for products other than Digitek®, which immediately preceded the use of that equipment for the production of Digitek®. That is, if the 50 cubic foot blender was used to blend a product other than Digitek®, ("product A"), and the blender was next used to blend Digitek® or one of its precursors, then the scope of discovery will include the batch record for product A. If records indicate that a blender was used for product A and was immediately thereafter used for Digitek®, a fair assumption can be drawn that the blender was not cleaned between uses. If compression and tableting equipment was used for product B immediately before a batch of Digitek®, then the batch record and associated testing data for product B is discoverable, including any indications of equipment malfunctions or the use of inappropriate dies. Assuming that a plaintiff experienced an adverse drug event or other injury associated with digitalis toxicity, and linked that event with the ingestion of Digitek®, it is the court's intention that such plaintiff should be able to trace backwards the lot number of his prescription to the manufacture of those tablets, and to determine the likelihood that the Digitek® contained only the ingredients it was supposed to contain, in the specified amounts. In light of the FDA warning letters, if the court were to refuse to expand discovery to records which reflect the use or misuse and operation or malfunctioning of equipment immediately before each batch of Digitek®, Plaintiffs would be unduly limited in their ability to determine whether a given batch of Digitek® was more likely than not "adulterated" and/or associated with an adverse drug event, other injury or death.

(# 150, pp. 15-16.)

In PTO # 52 entered on February 10, 2010, the court granted

Plaintiffs' motion to compel certain documents and deposition testimony of Paul Galea, Actavis Totowa LLC's Director of Quality Assurance Operations. Mr. Galea performed an audit of Actavis Totowa LLC in 2007, approximately one year before the Digitek® recall, and prepared an assessment report of Actavis Totowa operations. Defendants instructed Mr. Galea not to answer certain deposition questions based on the self-critical analysis, and the court rejected this argument. The court found that

> [e]ven if the report prepared by Mr. Galea does not mention Digitek® or any other drug by name, as the Actavis Defendants represent, to the extent it deals with Actavis Totowa's GMPs around the time of the FDA's warning letters and ultimate recall of Digitek® such information is highly relevant, and in the absence of an applicable privilege or other reason to avoid production, must be turned over to Plaintiffs.

(# 293, p. 12.)

Analysis

The court finds that Plaintiffs' Motion should be granted pursuant to Rule 37(a)(3)(B)(i) of the Federal Rules of Civil Procedure as outlined below and for the following reasons. The Actavis Defendants' objections to deposition questions related to products other than Digitek® were unfounded in light of the court's narrow expansion of discovery in PTO # 27 allowing inquiry into products produced before and after Digitek® using the same equipment. Furthermore, the court has reviewed the Affidavit of Mr. Dowling, the e-mail referenced above and his deposition testimony and believes that his Affidavit is misleading in light of

the e-mail and information subsequently developed in his deposition. The court relied on Mr. Dowling's Affidavit in narrowly defining the scope of discovery in PTO # 27. Had the undersigned known all of the information subsequently developed, the scope of discovery defined in PTO # 27 may have been different.

In any event, the Actavis Defendants' overly aggressive approach in depositions of instructing deponents to answer relevant questions only as to Digitek®, prevented Plaintiffs from obtaining discovery about cGMP of reasonably related products. The court subsequently made clear in PTO # 52 that Actavis Totowa's good manufacturing practices around the time of the FDA's warning letters and ultimate recall of Digitek® are highly relevant. Indeed, if the quality department's performance was not in compliance with applicable standards, the court cannot reasonably differentiate between quality control of other products and quality control of Digitek®. The court finds that Plaintiffs should have the opportunity to question witnesses with information about the quality department and cGMP, quality control and quality assurance at both the Little Falls and Riverview facilities (to the extent the quality department was moved to the Riverview facility) during the relevant time period before the 2008 shutdown of the Little Falls plant as to all drugs manufactured at the Little Falls plant. Plaintiffs should review the depositions already conducted and notify the Actavis Defendants of the individuals whom they wish to

redepose on these narrow issues. Plaintiffs indicated there were six to eight individuals at most. In depositions occurring in the future, Plaintiffs may inquire into these areas.

It is the court's hope that the parties will operate efficiently and in a cooperative manner in accomplishing this task. As before, the court reminds the parties that pursuant to PTO # 22, "[d]isputes arising during depositions that cannot be resolved by agreement and that, if not immediately resolved, will ... require rescheduling of the deposition, or might result in the need to conduct a supplemental deposition, shall be presented to Judge Goodwin or Magistrate Judge Stanley by telephone." (# 122, p. 9.) The parties could have avoided a time consuming and expensive discovery dispute had they followed this provision in PTO # 22 and, as the depositions proceed pursuant to this order, it is the court's hope that the parties will take advantage of the provisions in PTO # 22.

Accordingly, it is hereby **ORDERED** that Plaintiffs' Motion to Compel Deposition Testimony is **GRANTED** as outlined above.

The Clerk is directed to file this Order in 2:08-md-1968 which shall apply to each member Digitek®-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:10-cv-483. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided

by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: April 14, 2010

Mary E. Stanley
Mary E. Stanley
United States Magistrate Judge